REMARKS

This is response to the second Office action (Paper No. 20070210) mailed 23 February 2007.

Claims 1 through 4 and 6 through 18 are pending in this application.

Claims 8-18 were withdrawn from the examiner's consideration.

No new matter has been added.

Claims 1-3 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Gottlieb (EP 0230 052 A2) in view of Persselin (Clin Orthop Relat Res, 1991).

Claims 1 and 4 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Gottlieb EP'052 in view of Persselin and in view of L'Italien *et al.* (US 6,136,784).

Claims 1 and 6 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Gottlieb EP'052, in view of Persselin in view of Fletcher *et al.* (JCI, 1952) and in view of Harris (Diabetes Care, 1998).

Claims 1-3 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Gottlieb (US 4,710,380) in view of Gottlieb *et al.* (US 5,013,546) and in view of Persselin.

Claims 1 and 4 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Gottlieb'380 in view of Gottlieb *et al.*'546 in view of Persselin and in view of L'Italien *et al.*'784.

Claims 1 and 6 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Gottlieb'380 in view of Gottlieb *et al.*'546 in view of Persselin in view of Fletcher *et al.* and in view of Harris.

Claims 1-4 and 6-7 stand rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4, 8 and 13 of U.S. Patent No. 4,710,380 in view of U.S. Patent No. 5,013,546.

Claim 1 is directed to a method for controlling chronic inflammation in an individual having Metabolic Syndrome. The individual has Metabolic Syndrome and sequelae of chronic inflammation associated with the Metabolic Syndrome.

The examiner cites Gottlieb (EP 0230 052 A2 and U.S. Pat. No. 4,710,380) for showing the control of rheumatoid arthritis in an individual, and the treatment of a diabetic, which reads upon an individual having Metabolic Syndrome. The examiner also cites Persselin for showing that "rheumatoid arthritis necessarily reads upon a chronic systemic inflammatory disease and that..."

The examiner's reasoning is not proper.

The inventor of Gottlieb (EP 0230 052 A2 and U.S. Pat. Nos. 4,710,380 and 5,013,546) was the husband and professional colleague of the inventor of the present invention. Dr. A. Arthur Gottlieb (EP 0230 052 A2) mentions diabetes, and Gottlieb U.S. Pat. Nos. 4,710,380 mentions Type I diabetes. Even if Gottlieb (EP 0230 052 A2) does not specifically state that the diabetes is Type I diabetes, the diabetes in Gottlieb (EP 0230 052 A2) is Type I diabetes. Where diabetes is mentioned in Gottlieb (EP 0230 052 A2), it is mentioned in a list with rheumatoid arthritis, because it is an autoimmune disease and not because of any other relationship between the two. This is evidenced by other Gottlieb's patents such as U.S. Pat. Nos. 4,710,380 and 4,920,097. The examiner is taking the reference to diabetes out of proper context. The World Health Organization recognizes three main forms of diabetes: type I, type II, and gestational diabetes (occurring during pregnancy), which have some similar signs, symptoms, and consequences, but different causes and population distributions. Type I diabetes is an autoimmune disease which results in the destruction of Beta cells of the Islets of Langerhans which are located in the pancreas. The Beta cells produce insulin. Hence, their destruction results in a lack of insulin and the inability of the body to use glucose. That glucose then accumulates in the blood, resulting in elevated glucose. The elevated blood glucose of Type I diabetes is a result of hypoinsulinemia. Such individuals are typically underweight. There is no obesity associated with Type I diabetes, as there is in Type II diabetes and in the Metabolic Syndrome.

The examiner's reference to Persselin is also not proper. While Persselin's paper does refer to rheumatoid arthritis as a chronic inflammatory disease, he appears to be dealing with this

disease strictly from a clinical point of view. The cause of Rheumatoid Arthritis is an autoimmune reaction in which the joints are attacked by the patient's own immune system, resulting in damage to the joints. Such destruction subsequently results in chronic inflammation from rubbing of unprotected bone. Gottlieb, in his earlier patents discusses treatment of the autoimmune reaction, NOT the subsequent inflammation. Neither Gottlieb nor Persselin discuss a relationship or association between rheumatoid arthritis and the Metabolic Syndrome. Claims 1-3 are directed to the control of chronic inflammation in an individual having Metabolic Syndrome. That is, Claims 1-3 of the present application are directed to the control of chronic inflammation associated with Metabolic syndrome. The present invention teaches that since chronic antigenic stimulation resulting from immune dysfunction leads to the inflammatory condition which is characteristic of the Metabolic Syndrome, then correction of immune dysfunction can reduce the symptoms and characteristics of the Metabolic Syndrome, and thus the factors leading to Metabolic Syndrome related diabetes mellitus and coronary heart disease. Persselin does not disclose that the cause of rheumatoid arthritis is associated with Metabolic Syndrome. As stated above, the autoimmune reaction of Rheumatoid Arthritis, results in a decrease of joint cartilage and inflammation secondary to the joint bones rubbing against each other, without protection normally provided by the cartilage. What is important for the examiner to understand is that inflammation may be caused by many things.

The diabetes (similar to type II diabetes) that is referred to in the instant application is associated with the metabolic syndrome and obesity. That type of diabetes is associated with hyperinsulinemia, i.e., the end organs that are supposed to make use of the insulin in the blood do not respond to it properly. Since the cells of those organs do not receive and react to the

insulin properly, again, glucose accumulates in the blood despite an increasing level of insulin in the blood, but for a completely different reason than in Type I diabetes. Further, the instant application also makes reference to impaired glucose tolerance which is not the same as overt diabetes, and which may be a component of Metabolic Syndrome. Again, Metabolic Syndrome is unique and is not identical to any of the types of diabetes or any other condition. This fact has been recognized by the medical and scientific communities by assigning Metabolic Syndrome its own unique ICD-9 diagnostic code, viz. 277.7.

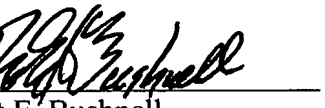
The use of a pharmaceutical composition selected from the group consisting of YG-Product, YGG-Product, Purified Leukocyte Dialysate Subfraction, and a combination thereof for controlling chronic inflammation in an individual having Metabolic Syndrome is neither taught nor suggested by the prior art.

Therefore, the examiner's reasoning is not proper.

No fee is incurred by this Amendment.

In view of the above, all claims are deemed to be allowable and this application is believed to be in condition to be passed to issue. Reconsideration of the rejections and objections is requested. Should any questions remain unresolved, the Examiner is requested to telephone Applicant's attorney.

Respectfully submitted,



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